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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,142	06/20/2003	Jean-Pierre Sommadossi	06171.IDX 1007 CON2	8280

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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,142	SOMMADOSSI ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89 and 130-177* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89 and 130-177* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of the U.S. Patent application SN 10/602,142 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed May 5, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 89, 130-131, 141, 143-144, 148, and 152-154 have been amended.

Claims 155-177 have been added

Claims 1-88 and 90-129 have been canceled.

Remarks drawn to rejections of Office Action mailed 11/15/2005 include:

102(b) rejection: which has been overcome by applicant's amendments and has been withdrawn.

103(a) rejection: which has been overcome by applicant's amendments and has been withdrawn.

An action on the merits of claims 89 and 130-177 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89 and 130-177 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of treating HCV with a modified compound which comprises a pyrrolopyrimidine as the base. The breadth of the claims is such that the support in the specification is not adequate for the claims. To provide adequate support for the breadth of the claims, applicant would have to provide sufficient evidence. An adequate representation of species requires that the species which are expressly described are indeed recognized in the art as representative of the entire genus. What constitutes "adequate representation" is an inverse function of the predictability in the art in question (should be supported by the state of the art). The written description requirement for a claimed genus, which in the instant application is a sugar-modified nucleotide analog comprising a pyrrolopyrimidine as a base, which comprises thousands of possible variations, may be satisfied through sufficient description of an adequate representation of species by functional characteristics sufficient to show applicant was in possession of the claimed genus. The entire disclosure of the instant application is seen to use

purines or pyrimidines as bases, not pyrrolopyrimidines, which are divergent in structure and function to purines and pyrimidines. There is no indication as to where the pyrrolopyrimidine is to be bonded to the sugar (i.e., is it linked to a ring nitrogen, or ring carbon) nor a teaching of which ring the attachment occurs, i.e. the pyrrole ring or pyrimidine ring.

The specification provides insufficient written description to support the pyrrolopyrimidine containing genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed", because applicants have never made the pyrrolopyrimidines, not contemplated making the pyrrolopyrimidines. (See Vas-Cath at page 1116.) The instant application is drawn to using purines and pyrimidines as bases, however, pyrrolopyrimidines were not mentioned or contemplated.

It is noted that the MPEP states that: the claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. However, the subject matter in question (pyrrolopyrimidine bases) was not in the claims as originally filed, but rather as filed in a preliminary amendment.

As such, a skilled artisan would not recognize the current evidence of record as sufficient evidence that applicants were in possession of the claimed genus of using pyrrolopyrimidine containing compounds.

It is noted that a rejection of the claims is reviewable by the Board of Patent Appeals and Interferences.

The written description requirement is separate and distinct from the enablement requirement. In re Barker, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See In re Armbruster, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) ("[A] specification which describes' does not necessarily also enable' one skilled in the art to make or use the claimed invention.").

It is noted that the "pyrrolopyrimidine" subject matter is not considered to be new matter as applicants included the subject matter in a preliminary amendment on the filing date. Moreover, it is also noted that the priority documents are also not seen to support pyrrolopyrimidines, as such, the instant application is not being afforded a status as a Continuation application, but rather a Continuation in Part, and as such, the newly claimed and unsupported subject matter is seen to get a priority date of 6/20/2003, not 5/23/2000.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-143, 148-152, 155-160, 165-168, 171-175 and 177 rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al. (2004/0063658).

The claims of the instant application are drawn to methods of treating HCV with a pyrrolopyrimidine containing nucleoside and methods of using combination therapy with the same.

Roberts et al. disclose methods of treating HCV with pyrrolopyrimidine containing compounds. See for example compounds: 92 on page 26; 162 on page 32; and 171 on page 34, for example. Roberts et al. disclose their compositions as tablets and comprising overlapping ranges with the instant claims (see formulation examples on page 92). Roberts et al. also teach their drugs can be used in combination therapy (see paragraph [0439]).

Claim Rejections - 35 USC § 103

Claims 89 and 130-177 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. as applied above and Ganguly et al. (US 6,277,830).

The instant application is drawn to methods of treating HCV with pyrrolopyrimidine containing compounds. Dependent claims limit the method to combination therapy.

Roberts et al. disclose methods of treating HCV with compounds overlapping in scope with those instantly claimed, as set forth supra. Roberts teach to administer their drugs to humans, in dosage forms overlapping with those instantly claimed, and in amounts overlapping with those instantly claimed, as set forth supra. Roberts et al. also teach their drugs can be used in combination therapy. What they do not teach is that they can be combined with the specific agents as set forth in the instant claims (i.e., with interferon, or ribavirin, for example).

Ganguly et al. teach that HCV drugs can be used in combination, such as with ribavirin, interferon, protease inhibitors, etc. (see column 3, lines 20-37).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. ***In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*** (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also ***In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960)*** (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and ***Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992)*** (mixture of two known herbicides held prima facie obvious).

Absent unexpected results, the combination as claimed is seen to be obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. Mcintosh
July 22, 2006

Shaojia A. Jiang
Supervisory patent examiner
Art Unit 1623